



UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Offic

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

PRICE, S

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 05/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/292,411	Applicant(s) Payne et al.
	Examiner Scott D. Priebe, Ph.D.	Group Art Unit 1632

Responsive to communication(s) filed on _____.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 11-24 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 11-24 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

In the original claim set, claim numbers 14 and 15 were skipped. Consequently, claims originally numbered as claims 16-26 were re-numbered as claims 14-24 as per 37 CFR 1.126, and applicant should correct their copy of the claims accordingly.

Claims 1-11 have been canceled by preliminary amendment.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 12 and 13, drawn to a polypeptide, classified in class 530, subclass 350.
- II. Claim 14, drawn to an antibody, classified in class 530, subclass 388.4.
- III. Claim 15, drawn to an antagonist or inhibitor of an enzyme, class and subclass dependent on species.
- IV. Claim 16, drawn to a method of treatment with a polypeptide, classified in class 424, subclass 94.4.
- V. Claim 17, drawn to method of gene therapy, classified in class 514, subclass 44.
- VI. Claim 18, drawn to method of treatment with an enzyme antagonist/inhibitor, classified in class 514, subclass dependent upon species of compound.
- VII. Claim 19, drawn to a diagnostic method comprising sequencing a nucleic acid, classified in class 435, subclass 6.

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- VIII. Claim 20, drawn to a diagnostic method comprising detecting a protein, classified in class 435, subclass 4.
- IX. Claim 21, drawn to a cell-based assay for an inhibitor of a polypeptide, classified in class 435, subclass 29.
- X. Claims 22 and 24, drawn to a method of vaccination using a polypeptide, classified in class 514, subclass 2+.
- XI. Claims 23 and 24, drawn to a method of immunization using nucleic acid expressing a protein, classified in class 514, subclass 44.

Claim 24 recites a misjoined Markush group in that the recited nucleic acid and protein do not share a common structural feature , a common function, or a common utility. Therefore, claim 24 was placed in invention X for the embodiment comprising a protein and in invention XI for the embodiment comprising a polynucleotide. If either group is elected, claim 24 should be amended to reflect the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

Invention I and inventions IV, VIII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention I can be used in

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any of the methods of inventions IV, treatment with a polypeptide; VIII, diagnostic assay for the polypeptide; and X, vaccination using the polypeptide.

Inventions II and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of invention II can be used to purify the polypeptide of invention I.

Invention III and inventions VI and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antagonist or inhibitor of invention III can be used in either the method of treatment of invention VI or the screening method of invention IX, in so much as the inhibitor would have been a known compound among others that were screened.

Inventions I, IV, VIII and X; invention II; inventions III, VI and IX; and inventions V, VII, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case

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the different inventions I-III are drawn to structurally and functionally different compounds, i.e. enzyme polypeptides, antibodies, and antagonists or inhibitors of the polypeptide. Each of these distinct compounds have different functions and effects. Inventions VII and XI, inventions IV, VIII and X; and inventions VI and IX are methods which use the structurally and functionally different compounds, and each of the sets of methods have different modes of operation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the complete search required for each invention is not required for each of the other inventions, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Art Jackson on 5/12/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasemine Chambers, can be reached on (703) 308-2035.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe

Scott D. Priebe, Ph.D.
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Technology Center 1600
Art Unit 1632